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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,273	07/25/2003	Laure Dumoutier	LUD 5543.4 DIV	7604

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,273

Applicant(s)

DUMOUTIER ET AL.

Examiner

Nirmal S. Basi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-52 is/are pending in the application.
- 4a) Of the above claim(s) 51 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

1. Amendment filed 7/25/06 has been entered.

Election/Restriction

2. Applicant's election of claim 50 (polynucleotide comprising SEQ ID NO:24) on 6/29/06, is acknowledged. The characterization of claim 50 as a polypeptide in the prior Office Action was in error. Claim 50 is drawn to isolated polynucleotide (nucleic acid). The correction called for by applicant is acknowledged. Applicant has correctly defined claim 50 as a polynucleotide and elected said claim, which corresponds to Group I, for further prosecution. Apart from the typographical error in the characterization of claim 50 applicant did not distinctly and specifically point out the supposed errors in the restriction requirement as to why Groups I-III are not distinct from each other. Therefore, the election has been treated as an election without traverse (MPEP 818.03(a)). Claims 51 and 52 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Objections

The disclosure is objected to because of the following informalities:

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78) as well as the relationship of instant application to the parent. Parent Application 09/751,797 is now Patent Number 7,081,528, Application 09/354,243 is now Patent Number 6,359,117, Application 09/178,973 is now Patent

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Number 6,274,710. The priority data must be updated to reflect the correct status of the priority documents.

4. Applicants are required to use the heading "Brief Description of the Drawings" to describe the drawings. See MPEP 608.01(f). On page 6, Applicant has written "BRIEF DESCRIPTION OF THE FIGURE" Appropriate correction is required.

Drawings

5. Drawings filed 4/19/01 are objected to by the Examiner.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because drawing sheets do not have the appropriate margin(s) (see 37 CFR 1.84(g)). Each sheet must include a top margin of at least 2.5 cm. (1 inch), a left side margin of at least 2.5 cm. (1 inch), a right side margin of at least 1.5 cm. (5/8 inch), and a bottom margin of at least 1.0 cm. (3/8 inch).. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Statutory Type Double Patenting Rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re*

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Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claim 50 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 12 of prior U.S. Patent No. 6,331,613. This is a double patenting rejection.

Although the wording of the claims is slightly different the claimed invention is exactly the same.

The difference in claim language is explained below. Claim 50 of instant application claims an isolated nucleic acid molecule **comprising** the nucleotide of SEQ ID NO:24. Base claim 12 of Patent No. 6,331,613 claims an isolated nucleic acid molecule **having** the nucleotide of SEQ ID NO:24. The words "having" and "comprising" are considered to have the same meaning as they relate to the claimed invention and encompass the same scope of the invention.

Claim 50 of instant application states, "encodes a T cell inducible factor". Base claim 1 of Patent No. 6,331,613 states "encodes a T cell inducible factor". Claim 12 depends on claim 1. Therefore the limitation of "encodes a T cell inducible factor" contained in claim 1 is inherent to claim 12 of the Patent No. 6,331,613.

Non-Statutory Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7 Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,331,613.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the isolated nucleic acid molecule of claim 50, recited in the instant application, encompasses an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:24. Claims 1 and 2 of U.S. Patent No. 6,331,613 also encompass an isolated nucleic acid molecule having or consisting of the nucleotide sequence of SEQ ID NO:24.

8. Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,081,528.

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Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 50 is drawn to isolated nucleic acid molecule, which encodes a T cell derived inducible factor comprising the nucleotide sequence of SEQ ID NO:24. Claims 1 of U.S. Patent No. 7,081,528 is drawn an isolated nucleic acid molecule which encodes a protein consisting of **all but about the first 20 amino acids of the protein** encoded by the nucleotide sequence set forth at SEQ ID NO:24. Claims 2 of U.S. Patent No. 7,081,528 is drawn an isolated nucleic acid molecule which encodes a protein consisting of **all but about the first 40 amino acids of the protein** encoded by the nucleotide sequence set forth at SEQ ID NO:24. Claims 3 of U.S. Patent No. 7,081,528 is drawn an isolated nucleic acid molecule which encodes a protein consisting of **all but the first 20 amino acids of the protein** encoded by the nucleotide sequence set forth at SEQ ID NO:24. Claims 4 of U.S. Patent No. 7,081,528 is drawn an isolated nucleic acid molecule which encodes a protein consisting of **all but the first 20 amino acids of the protein** encoded by the nucleotide sequence set forth at SEQ ID NO:24. Therefore claims 1-4 in U.S. Patent No. 7,081,528 differ from claim 50 in instant application in that they are missing a leader sequence of approximately 20 or 40 amino acids. Leader sequences routinely contain a sequence of signal amino acids or hydrophobic amino acids which would be cleaved of the molecule via the endoplasmic reticulum to provide a mature protein. The isolated nucleic acid molecule set forth as SEQ ID NO:24 is disclosed Patent No. 7,081,528.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to isolate or make the nucleic acid encoding to the full length protein disclosed in claims 1-4 of U.S. Patent No. 7,081,528. The nucleotide sequence for the truncated and full-length nucleic acids is disclosed in claims 1-4 of Patent No. 7,081,528. The ordinary artisan would have been motivated to isolate the nucleic acid of SEQ ID NO:24, encoding the full length protein, in order to isolate the leader sequence or to produce said protein in a host cell. The full-length protein containing the leader would be processed in the endoplasmic reticulum differently than the truncated form. The truncated and full-length nucleic acid can be used to study the functional characteristics of the encoded protein. Thus the claimed invention would have been prima facie obvious.

9. No claim is allowed.


Advisory

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/28/06


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